

**No. 24-1191**

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**United States Court of Appeals  
District of Columbia Circuit**

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NATIONAL ASSOCIATION OF MANUFACTURERS *and*  
AMERICAN CHEMISTRY COUNCIL,  
*Petitioners,*

– v. –

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY *and*  
MICHAEL S. REGAN, *in his official capacity as EPA Administrator,*  
*Respondents.*

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**PETITIONERS’ STATEMENT OF ISSUES TO BE RAISED**

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On April 26, 2024, EPA published the 2024 National Primary Drinking Water Regulation (the Rule), which sets a maximum contaminant level for six discrete polyfluoroalkyl substances, commonly known as PFAS. Petitioners challenge the Rule. The following statement of issues is made without prejudice to petitioners’ right to raise additional issues in their opening brief.

1. The Safe Drinking Water Act authorizes EPA to establish a maximum contaminant level (MCL) for contaminants known to occur in drinking water. *See* 42 U.S.C. § 300g-1(a). In establishing an MCL, EPA must consider the feasibility of achieving the level, taking cost into consideration; and determine generally

whether the cost of compliance is justified by the health benefits achieved. *See* 42 U.S.C. § 300g-1(b)(4)-(6). The first issue presented is whether EPA’s feasibility and cost-benefit analysis is unlawful for:

- a. considering only the lower costs and higher benefits of the Rule to large water systems, while expressly disregarding the higher costs and lower benefits of the Rule to small water systems serving one in six Americans;
- b. failing to conduct an analysis for each MCL individually and instead assessing the costs and benefits of multiple MCLs together;
- c. declining to weigh the costs of storing and disposing PFAS residuals given that PFAS are designated hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act; and
- d. declining to consider critical issues related to laboratory capacity necessary to comply with the new Rule.

2. The Safe Drinking Water Act authorizes EPA to establish an MCL “for each contaminant that the Administrator determines to regulate.” 42 U.S.C. § 300g-1(b)(1)(E). Congress directed EPA to set individual MCLs for each contaminant; it did not expressly authorize EPA to regulate mixtures of contaminants, as it has in other statutes. The second issue presented is whether EPA exceeded its statutory authority by setting a maximum contaminant level for mixtures of contaminants using a novel “hazard index” approach, in addition to the maximum levels for the constituent contaminants taken individually.

3. The Safe Drinking Water Act directs EPA to set maximum contaminant levels according to a two-step rulemaking process. First, “after consultation with the scientific community, including the Science Advisory Board,” and engaging in notice and comment, it must make a “preliminary determination” of “contaminants which . . . may require regulation.” 42 U.S.C. § 300g-1(b)(1)(B). Second, “[f]or each contaminant that [EPA] determines to regulate under” the foregoing procedure, the agency “shall publish maximum contaminant goals and promulgate, by rule, national primary drinking water regulations under this subsection.” *Id.* § 300g-1(b)(1)(E). The third issue presented is whether EPA violated the SDWA’s two-stage rulemaking procedures by:

a. announcing a preliminary determination to regulate PFHxS, PFBA, PFNA, and HFPO-DA, individually and as mixtures, at the same time that it issued the proposed maximum contaminant goals and levels for those substances and mixtures; and

b. failing to consult with the Science Advisory Board with respect to PFHxS, PFBA, PFNA, or HFPO-DA, individually or as mixtures.

4. The Safe Drinking Water Act requires EPA to use “the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices” when promulgating maximum contaminant levels. 42 U.S.C. § 300g-1(b)(3)(A)(i). The fourth issue presented is whether EPA failed to satisfy this standard by, among other things, violating its own

guidance and procedures designed to ensure acceptable data quality and good statistical practice, or otherwise by using data and analyses that were rejected as inadequate by its own Science Advisory Board.

Dated: July 10, 2024

Respectfully submitted,

/s/ Michael B. Kimberly

MICHAEL B. KIMBERLY

PAUL W. HUGHES

CONNOR J. SUOZZO

NICOLE E. WITTSTEIN

*McDermott Will & Emery LLP*

*500 North Capitol Street NW*

*Washington, DC 20001*

*(202) 756-8000*

*Counsel for Petitioners*

**CERTIFICATE OF SERVICE**

I hereby certify that on July 10, 2024, I electronically filed the foregoing with the Clerk of this Court using the CM/ECF system, and counsel for all parties will be served by the CM/ECF system.

Dated: July 10, 2024

/s/ Michael B. Kimberly